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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/926,394 | 10/25/2001 | Masaru Hosokawa | 215103US0PCT | 9972 |

22850 7590 09/25/2003

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1940 DUKE STREET
ALEXANDRIA, VA 22314

| EXAMINER |
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AZPURU, CARLOS A

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1615

DATE MAILED: 09/25/2003 //

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/926,394

Applicant(s)

HOSOKAWA ET AL.

Examiner

Carlos A. Azpuru

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Receipt is acknowledged of the extension of time and amendment filed 07/07/03.

As requested, the applicant has been provided with the English translations of the Japanese references requested. Since applicant did not respond to the rejections on the merits regarding these Japanese references, the following rejection is maintained in this action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-23 are rejected under 35 U.S.C. 102(b) as being anticipated by JP60-123416 (JP'416).

JP'416 disclose a transdermal composition comprising a mixture of polymers which forms a surface-segregated film, and active ingredient. The polymers have different surface tension and are a combination of hydrophobic and hydrophilic polymers, with one being a silicone polymer or a polymer having a fluorinated carbon chain and a hydrophilic polymer. The hydrophilic polymer may be a polyvinyl alcohol (see claims and example 2). The instant claims are anticipated by JP'416.

Art Unit: 1615

Claims 1-23 are rejected under 35 U.S.C. 102(b) as being anticipated by JP3-11530 (JP'530).

JP'530 disclose a transdermal composition comprising a mixture pf polymers which forms a surface-segregated film, and active ingredient. The polymers have different surface tension and are a combination of hydrophobic and hydrophilic polymers, with one being a silicone polymer or a polymer having a fluorinated carbon chain and a hydrophilic polymer. The hydrophilic polymer may be a polyvinyl alcohol (claims; page 6, lines 3-18; page 7, lines 6-15). The instant claims are anticipated by JP'530.

Claims 1-23 are rejected under 35 U.S.C. 102(b) as being anticipated by JP2000-44476 (JP'476).

JP'476 disclose a transdermal composition comprising a mixture pf polymers which forms a surface-segregated film, and active ingredient. The polymers have different surface tension and are a combination of hydrophobic and hydrophilic polymers, with one being a silicone polymer or a polymer having a fluorinated carbon chain and a hydrophilic polymer (see claims). The instant claims are anticipated by JP'476.

Claims 1-23 are rejected under 35 U.S.C. 102(b) as being anticipated by JP62-240612 (JP'612).

Art Unit: 1615

JP'612 disclose a transdermal composition comprising a mixture of polymers which forms a surface-segregated film, and active ingredient. The polymers have different surface tension and are a combination of hydrophobic and hydrophilic polymers, with one being a silicone polymer or a polymer having a fluorinated carbon chain and a hydrophilic polymer (see claims). The instant claims are anticipated by JP'612.

Claims 1-23 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by JP05-112423 (JP'423).

JP'423 disclose a transdermal composition comprising a mixture of polymers which forms a surface-segregated film, and active ingredient. The polymers have different surface tension and are a combination of hydrophobic and hydrophilic polymers, with one being a silicone polymer or a polymer having a fluorinated carbon chain and a hydrophilic polymer. Specific polymers include an oxazoline-modified organopolysiloxane having an organopolysiloxane segment (a) and a poly(N-acylalkyleneimine) segment bonded to it at the end or side chain via a hetero-atom-containing alkylene group. The hydrophilic polymer may also be a polyvinyl polymer.

Art Unit: 1615

The polymer has the same weight range and weight ratio of segments A to B (see abstract, entire document). The claims are clearly anticipated by JP'423.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

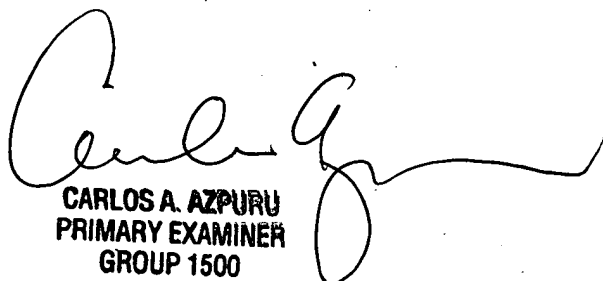
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is 703/308-0237. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Art Unit: 1615

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

ca



CARLOS A. AZPURU
PRIMARY EXAMINER
GROUP 1500